Octadecylamine

Processing

Chemical Name(s):
Octadecylamine

CAS Number:
124-30-1

Other Names:
1-Aminooctadecane, 1-Octadecanamine, adagenen 142, Alamine 7, Alamine 7D, Armeen 118D, Armeen 18D, Armofil, Kemamine P990, N-Octadecylamine, N-Stearylamine, Nissan Amine AB, Stearamine, Stearylamine, ODA

Other Codes:
NIOSH Registry Number: RG4150000

Summary of Advised Recommendation*

Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Synthetic	*Prohibited*	*None.*

Characterization

Composition:
$C_{18}H_{39}N$

Properties:
Opaque, off-white liquid with ammoniacal odor; insoluble in water but soluble in alcohol, ether, benzene; very soluble in chloroform; miscible in acetone; boiling point 346.8 deg C at 760 mm Hg; melting point 52.9 deg. C; molecular weight 269.51; specific gravity 0.8618 at 20 deg C/ 4 deg. C.

How Made:
ODA is produced by catalytic hydrogenation of stearyl nitrile, which itself is the product of stearic acid and nitride. Stearic acid is an 18-carbon saturated fatty acid found in tallow, coconut, soya, palm kernel and palm. The highest levels—over 19%—are found in tallow. Nitride is produced by passing ammonia over a heated metal.

Specific Uses:
Boiler water additive used to prevent the corrosion of boiler equipment and their distribution lines; used as a mold release agent in manufacture of battery cases; chemical intermediate for octadecyl isocyanate; chemical intermediate for other surface-active agents; anticaking agent; flotation agent; agents in various aspects of petroleum industry; antistripping agent in asphalt emulsions for highways.

Action:
Octadecylamine forms a molecularly thin film on the interior of steam lines. This boiler water additive prevents corrosion by preventing carbonic acid formed from carbon dioxide captured within the steam from coming into contact with the steam lines. ODA also has surfactant properties.

Combinations:
Used in combination with ammonium hydroxide and various volatile amines (cyclohexylamine, diethylaminoethanol, and morpholine).

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* *This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed and commented on by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA (7 USC 6517(m)). The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and is not intended to incorporate commercial availability, socio-economic impact, or any other factor that the NOSB and the USDA may want to consider in making their decisions.*

Status

OFPA
May be added to the National List as an equipment cleaner [7 USC 6517(c)(1)(B)(i)].

Regulatory
FDA—[21CFR Sec.173.310] Boiler water additives; not to exceed 3ppm in steam and excluding use of such steam in contact with milk and milk products.

EPA/NIEHS/Other Appropriate Sources

EPA - Does not appear on any of the EPA's lists of hazardous substances (EPA, 1998b).

NIEHS - National Toxicological Program (NTP, 2001)
Acute Toxicity:

dose	mode	specie	amount	unit
LD50	ipr	mus	250	mg/kg

Sax Toxicity Evaluation: Not available

Carcinogenicity: Not available

Mutagenicity: Not available

Teratogenicity: Not available

Standards, Regulations & Recommendations:
OSHA: None
ACGIH: None
NIOSH Criteria Document: None
NFPA Hazard Rating: Health (H): None
Flammability (F): None
Reactivity (R): None

Other Toxicity Data:
Skin and Eye Irritation Data:
skn-rbt 500 mg/24H MOD
Review: Toxicology Review
Status: Reported in EPA TSCA Inventory, 1980

Acute/Chronic Hazards:
Exposure to this compound may cause sensitization of the skin.

Minimum Protective Clothing:
If Tyvek-type disposable protective clothing is not worn during handling of this chemical, wear disposable Tyvek-type sleeves taped to your gloves.

Recommended Respirator:
Where the neat test chemical is weighed and diluted, wear a NIOSH-approved half face respirator equipped with an organic vapor/acid gas cartridge (specific for organic vapors, HCl, acid gas and SO_2) with a dust/mist filter. Splash proof safety goggles should be worn while handling this chemical. Alternatively, a full face respirator, equipped as above, may be used to provide simultaneous eye and respiratory protection.

Storage Precautions:
You should keep this material in a tightly-closed container under an inert atmosphere, and store it at refrigerated temperatures.

Spills and Leakage:
If you spill this chemical, FIRST REMOVE ALL SOURCES OF IGNITION, then dampen the solid spill material with toluene, then transfer the dampened material to a suitable container. Use absorbent paper dampened with toluene to pick up any remaining material. Your contaminated clothing and absorbent paper should be sealed in a vapor-tight plastic bag for eventual disposal.

Solvent-wash all contaminated surfaces with toluene followed by washing with a soap and water solution. Do not reenter the contaminated area until the Safety Officer (or other responsible person) has verified that the area has been properly cleaned.

Skin Contact:
IMMEDIATELY flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water.
IMMEDIATELY call a hospital or poison control center even if no symptoms (such as redness or irritation) develop.
IMMEDIATELY transport the victim to a hospital for treatment after washing the affected areas.

Inhalation:
IMMEDIATELY leave the contaminated area; take deep breaths of fresh air. If symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop, call a physician and be prepared to transport the victim to a hospital. Provide proper respiratory protection to rescuers entering an unknown atmosphere. Whenever possible, Self-Contained Breathing Apparatus (SCBA) should be used; if not available, use a level of protection greater than or equal to that advised under Respirator Recommendation.

Eye Contact:
First check the victim for contact lenses and remove if present. Flush victim's eyes with water or normal saline solution for 20 to 30 minutes while simultaneously calling a hospital or poison control center.

Do not put any ointments, oils, or medication in the victim's eyes without specific instructions from a physician.

IMMEDIATELY transport the victim after flushing eyes to a hospital even if no symptoms (such as redness or irritation) develop.

Ingestion:
DO NOT INDUCE VOMITING. Corrosive chemicals will destroy the membranes of the mouth, throat, and esophagus and, in addition, have a high risk of being aspirated into the victim's lungs during vomiting which increases the medical problems.

If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and IMMEDIATELY call a hospital or poison control center. IMMEDIATELY transport the victim to a hospital.

If the victim is convulsing or unconscious, do not give anything by mouth, ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. DO NOT INDUCE VOMITING. Transport the victim IMMEDIATELY to a hospital.

Status Among U.S. Certifiers
Not allowed by any U.S. Certifier. See the discussion in the background paper Steam Generation in Organic Food Processing Systems (Steam Paper).

International
Canada – Not included in the list of permitted non-organic additives substances for organic food products (CGSB, 1999).

CODEX- Not in Annex 2, Table 4, 'Processing Aids' (FAO/WHO, 1999).

EU 2092/91 – Not in Annex VI, 'Processing Aids' (EU 2092/91).

IFOAM – Not on Appendix IV, approved processing aids and other products (IFOAM, 2000).

Japan — Not on the list of approved food additives (Woolsey, 2000).

OFPA 2119(m) Criteria

(1) The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems.
As this is a processing material, the substance is not used in organic farming systems. Chemical interactions within a processing environment are discussed in the Steam Paper.

(2) The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.
See processor criteria (3) below.

(3) The probability of environmental contamination during manufacture, use, misuse or disposal of such substance.
This is considered below under item (2).

(4) The effect of the substance on human health.
This is considered in the context of the effect on nutrition (3) below as well as the consideration of GRAS and residues (5) below.

(5) The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.
As this is not released into the agroecosystem, there is no direct effect.

(6) *The alternatives to using the substance in terms of practices or other available materials.*
See discussion of alternatives in the Steam Paper.

(7) Its compatibility with a system of sustainable agriculture.
This is considered more specifically below in the context of organic handling in (6) below.

Criteria from the February 10, 1999 NOSB Meeting

A PROCESSING AID OR ADJUVANT may be used if;

1. It cannot be produced from a natural source and has no organic ingredients as substitutes.
When considering chemical means to condition steam lines in boiler systems, the additives to the steam lines must be volatile, so that they purposely travel along with the steam. There are no known non-synthetic boiler additives that can serve this purpose. However, steam can be produced from water without the addition of boiler water additives. A list of substances that are FDA approved for boiler water contact is attached. While these are not direct substitutes, these are available options. The NOSB has already recommended that several of these be listed. See the Steam Paper for more discussion.

2. Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling.
Octadecylamine (ODA) is manufactured from stearic acid and ammonia. Stearic acid is a fatty acid derived from beef tallow and other natural sources. The impact of ammonia is covered in the TAP review on ammonium hydroxide. Catalytic hydrogenation entails a significant use of energy in addition to that expended for ammonia production.

The material is an irritant, and needs to be handled as such. There are no instructions or restrictions for disposal (EPA, 1998b). Properly handled, its environmental impacts appear to be negligible. However, both surfactant and amine properties may be harmful to aquatic life if discharged into water. Octadecylamine can be poisonous by intraperitoneal routes, and is a skin irritant (Lewis, 1989) and a severe eye irritant (Akzo Chemie, 1995). Fatty alkylamines are generally considered skin and eye irritants, but generally not a hazard by inhalation routes (Visek, 1992). When heated to decomposition, it produces toxic fumes of NO_x (Lewis, 1989).

3. If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.
The effects of the addition of octadecylamine to the processing stream on the nutritional or other quality of food does not appear to have been studied. Octadecylamine is a moderately toxic compound that is considered poisonous when ingested (Lewis, 1989). Rated as 3 on a scale of 1-5 or moderately toxic (Gosselin, Smith, and Hodge, 1984). One source states that primary amines with very long alkyl chains, such as octadecylamine, are regarded as practically

non-toxic, and some lab animals have tolerated high doses for long periods (Greim, et al., 1998). However, researchers have noted histological changes in the lymph nodes, gastrointestinal mucosa and liver of test animals (Gosselin, Smith, and Hodge, 1984). One study noted that laboratory animals with long-term exposure to this material produced some intestinal tract cellular aberrations (Deichmann, et. al, 1958).

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*
The primary use is to prevent corrosion of boiler and steam line equipment. It is not intended to have any functional effect on the food, but will carry over into the steam that is in direct food contact. It does not serve as a preservative, or to recreate/improve flavors, colors, textures, or nutritive value lost during processing.

5. *Is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
Octadecylamine is not Generally Recognized as Safe (GRAS). The FDA sets a threshold for its use in steam that is in contact with food because of its toxicity. There is no Food Chemicals Codex monograph.

6. *Its use is compatible with the principles of organic handling.*
Organic standards are precautionary when evaluating synthetic substances used in food. Volatile amines in general do not appear to be compatible with the principles of organic handling. They are synthetic, toxic, and are not necessary to produce any food. Even though octadecylamine appears to be the least toxic of the compounds, it still has environmental impacts of the manufacturing process and the adverse health effects from exposure that do not fit within organic principles. Food processors generated and used steam for a long time without these chemicals. Many organic food processors have already adopted viable and practical ways to address corrosion. This is further discussed in the Steam Paper, as well as in the TAP Reviewers' comments.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*
Again, culinary steam can be produced without the use of this chemical. See the Steam Paper and the TAP Reviewers' comments for a further discussion.

TAP Reviewer Discussion*

Reviewer 1 *[Food Science and Nutrition Professor with inspection and certification experience]*
Octadecylamine is . . . a synthetic compound . . . intended to function similarly to a coating on the inside walls of the steam pipes. Fatty amines which contain alkyl chains of 10 to 14 carbons are considered more irritating than fatty amines containing 1 to 18 carbon atoms such as octadecylamine which is $C_{18}H_{39}N$ from a health and safety issue. Overall oral and dermal toxicity has been reported to be moderate and is not considered an inhalation hazard at ambient conditions because of its low volatility. However, inhalation of its heated vapor such as in steam may result in irritation of the nose, throat and upper respiratory system.

[ODA] is not allowed by any US certifier *[or]* any international certification agency.
. . .
Octadecylamine is used with a combination of emulsifiers and in some cases neutralizing amines (Betz, 1980). The film is spread out giving more uniform *[coverage]* and increasing the protection afforded by the filming amine.

Even though the reactivity of ODA is generally less than the neutralizing amines, since it is blended with other volatile components or ingredients especially neutralizing amines, it clearly is not consistent with sound organic principles and sustainability. It is considered poisonous when ingested and is not generally recognized as safe. My conclusion is that it be prohibited from all organic food processing operations where there is direct contact of the steam to the organic food being processed. As a prohibited boiler additive, I do not feel this will present an unsolvable issue with large scale organic food processors since there are a number of options used individually or collectively to insure boiler-steam line integrity and overall energy efficiency. These options include boiler feed water treatments and/or installation of stainless steel steam lines as noted previously.

* *OMRI's information is enclosed in square brackets in italics. Where a reviewer corrected a technical point (e.g., the word should be "intravenous" rather than "subcutaneous"), these corrections were made in this document and are not listed here in the Reviewer Comments. The rest of the TAP Reviewer's comments are edited for identifying comments, redundant statements, and typographical errors. Any text removed is identified by ellipses [. . .] Statements expressed by reviewers are their own, and do not reflect the opinions of any other individual or organization.*

Advised Recommendations to the NOSB
1. Synthetic
2. Prohibited
3. Suggested annotation: prohibited for processing operations where there is direct steam to food contact.

Reviewer 2 *[Consultant to organic certifiers]*
Octadecylamine is a synthetic material . . . use*[d]* as an additive to steam that comes into direct contact with organic foods during processing. . . It is interesting to note that the levels of octadecylamine permitted in contact with foods during processing is lower [more strict] than those set for morpholine, diethylaminoethanol, *[and]* cyclohexylamine. . .

Historically, NOSB recommendations have been against the contact of any synthetic boiler additives with organic foods. All organic production and processing standards are in agreement that toxic substances should not contaminate organic foods. Organic certifiers in the United States, if they take a position at all on this issue, are consistent in repeating the prohibition recommended by the NOSB. Of all volatile amines used in food processing systems, octadecylamine is perhaps the least toxic, but it is nonetheless synthetic, it does have some deleterious affects on health from exposure, and does not pose any benefits to the nutritional qualities of foods. Ammonium soaps have been prohibited *[for handling]* by the NOSB (OMRI, 2001).

Live steam can be and is produced in many processing systems without the use of any boiler additives that carry over onto the food products. Boiler water can be treated in advance of use in the system by a variety of methods to soften, deionize, filter, and otherwise purify it. These steps reduce the need for addition of synthetic materials not on the National List to the boiler system. In some applications, the steam or heating system for the food may be changed to one where live steam is not the active agent, but rather heating (of food contents directly, or of steam in contact with food) is done via a heat exchange system. The wide variety and individuality of processing systems which exist is indicative of the many ways in which the full range of processed food products can be made, without the need for toxic boiler additives to be used in contact with organic foods. This reviewer does not know of any food product type that absolutely requires octadecylamine in steam which contacts organic food.

Justification of use of octadecylamine by the petitioners is based on the constraints of their particular boiler and steam systems as they currently exist, and on the financial and/or logistical challenges involved with changing those systems so as to avoid contact of the organic food by the octadecylamine. However, economic considerations are clearly not one of the criteria (either in OFPA or the final NOP rule) for determining the suitability of materials used in organic production systems.

History shows that . . .an organic operator (producer or handler) has had to make substantial changes to their system in order to be compliant with organic standards. These changes often involved redesigning of systems, practices, and techniques. In many cases, such changes resulted in the need for financial investment, as well as an investment in time. Some creativity on the part of the operator was often needed, to devise a new system. This has indeed been the case for certain processors, who made adjustments to their boiler systems or manufacturing practices in order to comply with the prohibition of contact of organic foodstuffs by synthetic boiler chemicals. The inconvenience of having to retool or readjust systems should not be the determining factor in whether or not such materials are added to the National List.

For certain processors, where organic processing events are not frequent, the boiler may be operated without the octadecylamine for a limited time, without significant affect on the boiler or steam line system. For these operations, no retooling may be needed; instead, a procedure can be designed whereby it is verifiable that the volatile boiler chemical has been exhausted from the system prior to handling the organic goods.

For processors who intend to process frequently enough, or for long enough run times, redesigning of the system will be necessary, in one way or another. Prohibition on the use of volatile boiler chemicals can exist without consigning processors to premature deterioration of their equipment. It is often the case in industry that the creative process involved in redesigning systems has unpredicted benefits (short- and long-term) to the operator and the environment, in terms of long-term cost-effectiveness and sustainability; efforts in this direction should be encouraged, especially if not doing so results in a compromise of organic principles.

In fact, running boiler equipment designed for use with synthetic additives without the additives in place does lead to deterioration, and consequent lower efficiency of the system, which generally means greater energy consumption (Kohan, 1997). While greater efficiency of energy consumption seems undoubtedly to be desirable (both economically and ecologically), energy balance as a whole has not been considered as factor by the NOSB or certifiers when making determinations on the compatibility or allowability of materials or methods. To use such a factor as a criterion in the case

for the volatile boiler additive is therefore inconsistent with the rest of the paradigm, and should not be a determining factor at this time.

Advised Recommendations to the NOSB
Octadecylamine should be deemed a synthetic, prohibited material, and not be added to the National List for any purpose.

Reviewer 3 *[University staff in Food Science with inspection, consulting, and certification experience]* Octadecylamine (ODA) is . . . a steam additive chemical to reduce corrosion in pipes. There could be direct food contact in many processing operations when steam is used to cook or heat food, such as in a blancher, cooker, canner, or other operations. ODA has no functionality toward the food. Much of the petition was such a poor copy as to be illegible. The sections were not numbered so those that are illegible could not be identified.

Comments Based on the Criteria
Octadecylamine is manufactured from stearic acid (derived from beef tallow) and ammonia. These potentially might be available from a natural source, but no indication is made in the petition to use natural sources, nor is there discussion of potentially acceptable manufacturing practices.

Octadecylamine is an irritant and must be handled properly. Octadecylamine is rated as poisonous when ingested and as moderately toxic. In spite of this lab animals have tolerated high doses for long periods. It would appear that it has no adverse effects on human health if used as intended.

The justification for use of ODA is no different than trying to justify the use of a synthetic herbicide like Round-Up for organic farming, just because it provides a cheaper alternative to weed control and does not leave any detectable residue. Organic handling isn't about economics or end product testing, it's the process that's critical when evaluating compatibility with organic principles. Food processors generated and used steam for a long time without these chemicals. Many organic food processors have already adopted viable and practical ways to address corrosion without the use of ODA.

There are other solutions that could be used to produce the desired result (no corrosion of piping). To summarize many of the citations reviewed, 'use of stainless steel piping completely solves the problem of corrosion.' The justification statement in the petition and the alternative control methods do not mention this as a possible solution. They do mention the costs of capital equipment and provide anecdotal evidence of the life expectancy and replacement needs should boiler water additives not be used, but provide no data to support this. There are numerous tests that can and should be performed periodically to determine the corrosion rates, (even with the use of inhibitors) to insure that equipment is being operated and maintained in a safe and efficient manner. Without confirming studies to show the differences in corrosion rates with and without the use of corrosion inhibitors, it appears that these petitioners are using anecdotal evidence to justify their continued use of cheap toxic chemicals instead of more expensive, but viable alternatives. There are several cited alternatives: stainless steel piping (suitable for all operations); discontinued use during organic processing (some operations); steam to steam heat exchanger (suitable for some operations); secondary boiler for food contact application only (suitable for all operations) that could be used. None of these are necessarily cheap, but all offer a viable alternative to the use of toxic chemicals.

Advised Recommendations to the NOSB
In spite of the low health and environmental impact of ODA, alternatives exist with even lower impacts. Octadecylamine should not be approved for use as a boiler chemical for organic production.

Conclusion
The reviewers unanimously consider octadecylamine to be synthetic, and unanimously advise the NOSB to not add octadecylamine to the National List. Use should remain prohibited in organic handling.

References

See the Steam Paper.